

FILED

IN THE UNITED STATES DISTRICT COURT
FOR EASTERN VIRGINIA

2011 DEC 27 P 4:43

CLERK US DISTRICT COURT
ALEXANDRIA, VIRGINIA

John Farrell, NMD
PO Box 19803
Asheville, NC 28815

Plaintiff,
Pro Se

v.

HON. DAVID J. KAPPOS
Under Secretary of Commerce for
Intellectual Property and Director of the
United States Patent and Trademark Office
Office of General Counsel,
United States Patent and Trademark Office
Madison Building East, Rm. 10B20
600 Dulany Street, Alexandria, VA 22314

Defendant.

1:11CV1397
GBL/IDD

COMPLAINT

Plaintiff, John Farrell ("Plaintiff", "Farrell"), for its complaint against the Honorable
David J. Kappos, states as follows:

NATURE OF THE ACTION

1. This is a pro se action by the inventor of United States Patent 7,968,119 ("the '119 patent") seeking judgment, pursuant to 35 U.S.C. § 154, that the patent term adjustment for the '119 patent be changed from 621 days to a minimum of 17 years from issuance date of the '119 patent.

2. This action arises under 35 U.S.C. § 154 and the Administrative Procedures Act, 5 U.S.C. §§ 701- 706.

JURISDICTION AND VENUE

3. This Court has jurisdiction to hear this action and is authorized to issue the relief sought pursuant to 28 U.S.C. §§ 1331 and 1361; 35 U.S.C. §154(b)(4)(A) and 5 U.S.C. §§ 701- 706.

4. Venue is proper in this district by virtue of 35 U.S.C. § 154 in conjunction with the American Inventor Act of 2011.

5. The complaint is timely in accordance with 35 U.S.C. § 154(b)(4)(A).

THE PARTIES

6. Plaintiff Farrell is the Inventor, Pro Se of the '119 patent under the laws of the United States, having a principal place of residence at 5460 SW 7th Ave Road, Ocala, FL 34471 and current seasonal mailing address of PO Box 19803, Asheville, NC 28815.

7. Defendant David J. Kappos ("Director") is the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

("PTO"; "Office"), acting in his official capacity. The Director is the head of the agency, charged by statute with providing management supervision for the PTO and for the issuance of patents. The Director is the official responsible for determining the period of patent term adjustment under 35 U.S.C. § 154. The Defendant is also responsible for ensuring the agents of the PTO adhere to the Manual of Patent Examining Procedure (MPEP), Chapter 37 (Intellectual Property Regulations) of the Code of Federal Regulation (C.F.R.), and Title 35 (Patents) of the United States Code (U.S.C.) during each patent examination.

BACKGROUND

8. It has been said that legislative history regarding patents has made clear the objective to ensure that "no applicant diligently seeking to obtain a patent will receive a term of less than seventeen years." Although the Plaintiff admits to being legally inexperienced and is further challenged by specific learning disabilities, he asserts that these are not compelling reasons to deny his exercise of his Constitutional rights to protect his intellectual property via the PTO and to petition the appropriate Federal District Court and to expect to receive equal protection and due process under the law especially in the face of a government agency using his lack of legal expertise against him and showing preference for another applicant over whom the Plaintiff has priority. A review of the history of the prosecution of the '119 patent will demonstrate beyond doubt that the Plaintiff was, at all times and to this day, diligently seeking to obtain his patent and receive a minimum of a 17-year term as intended by historical legislative intent while

striving to overcome the instant prejudice and deliberate obstacles set before him by the PTO due to the nature of his invention and his non-affiliation with any “known commodities to the Office”. The Plaintiff asserts that the stipulations in 35 USC § 154, which limits the patent term adjustment of one who has been forced to file a Request for Continued Examination (“RCE”) by a partisan Examiner supported by an equally biased Supervising Patent Examiner (“SPE”), is neither fair nor equitable and contrary to the intention of the law.

9. Beginning in 1999, Plaintiff Farrell undertook to find a solution to the spreading public health problem of abuse and diversion of prescription narcotic pain medications, which resulted in his filing a provisional patent application (“PPA”) with the PTO on 6/26/2001. The non-provisional patent application #10/183,678 (the ‘678 application, “‘678”) was filed with the PTO on 6/26/2002. The claims of the ‘119 patent, entitled “Tamper-Proof Narcotic Delivery System” are directed to a novel three-component pharmaceutical formula for narcotic compositions and methods for treatment of moderate to severe pain. The Plaintiff is the inventor and owner of U.S. patent 7,968,119 issued a full 9 years and 2 days after the filing of the ‘678 application. According to the PTO, the average time for a patent to be examined is approximately 35 months. Due to the amount of delayed pendency directly attributable to the PTO and the stipulations in 35 USC §154, the Plaintiff has lost at least 4.25 years from his patent term and seeks redress.

EXHIBIT A – US Patent 7,968,119 (“the ‘119 patent”)

EXHIBIT B – the 10/183,678 application Image File Wrapper, (“IFW”, “PAIR”)

EXHIBIT C – the 10/183,678 application Transaction History, (“PALM”)

EXHIBIT D – Board of Patent Appeals and Interference decision, 11/10/2010, p. 15-17

10. The '119 patent was allowed only after the Plaintiff filed a Notice of Appeal with the Board of Patent Appeals and Interference ("BPAI") on 2/10/2009, followed by an Appeal Brief on 7/2/2009, which resulted in a BPAI Decision on 11/10/2010 in which the Examiner was Affirmed in Part only. The essential parts in which the Examiner was overturned by the BPAI included the entire recitation of "112 Written Description" rejections the Examiner had held to since the 1st Office Action of 1/26/2004, "112 New Matter" rejections the Examiner had held since specifically instructing the Plaintiff in an Interview to cancel his Original Claims in their entirety and rewrite and submit New Claims in July 2006 when the Plaintiff had just become an Inventor, Pro Se. The Examiner was also overturned on a pivotal "103 Obvious" rejection related to two dependent claims, which simply needed to be cancelled and incorporated into the two independent claims. Except for one Final Office Action on 9/25/2007, in which the years of "103 Obvious" rejections were inexplicably dropped, only to be revived again in the next Non-Final Office Action on 3/27/2008, the Examiner held to "103 Obvious" rejections in various forms from the first Office Action of 1/26/2004 throughout the prosecution. This partial reversal of the Examiner's 9 years of rejections resulted in the amendment, allowance and subsequent issuance of the '119 patent on 6/28/2011, with a meager 621 day patent term adjustment despite the Examiner's assurances to the Plaintiff throughout the prolonged prosecution that he would be given his full patent term back once the claims were allowed and issued.

11. The '119 patent term commenced from the filing of the '678 application 6/26/2002 and is hampered by the RCE the Examiner forced on the '678 application on 5/5/2005 during which time Plaintiff had legal counsel. It will become evident later in this complaint why the "missing Office Action" of 12/10/2004, which was not received by the Plaintiff's attorney in the mail leading to a denial of a re-aging request on 4/11/2005 and an Extension of Time, and RCE on 5/5/2005 may have been contrived. Another RCE was filed 7/19/2006 after the Examiner refused to enter the Plaintiff's pro se status and mailing address into the system but did take time to urge the inexperienced inventor to cancel his original claims and write new ones. And yet another RCE was filed by the Plaintiff, on the express advice of the Examiner as she argued fervently in December 2007 fervently against the Plaintiff presenting the intellectual property contained in the '119 patent to the Board of Patent Appeals and Interference with distinct promises of allowance if the Plaintiff would instead file an RCE and submit the negotiated amendments to her for her signature. The RCEs have negatively effected the Patent Term Adjustment due to the specific stipulations regarding RCE in 35 USC § 154. The Plaintiff contends that the claims recited in the '119 patent, except for those amendments made after the BPAI decision which led to issuance, were not amended in any appreciable manner after the Plaintiff's 12/27/2007 Reply to the Final Office Action of 9/25/2007. RCE forms and instructions fail to warn the applicant of the serious loss of patent years that may come with an RCE. During a recent phone call on 11/12/2011 with the PTA representative in the Legal Administration Office of the PTO, the representative stated unequivocally that there "appeared to be at least 4 years in which the claims did not change noticeably" and that there may be "other areas" in which delay could be

attributable to the PTO, but the statutory requirements of 35 U.S.C. §154 are inescapable: the Plaintiff could now only pursue one of two remedies – Congress or Federal District Court action.

EXHIBIT B– IFW – RCEs filed 5/5/2005, 7/19/2006, and 12/12/2007.

12. For the purpose of this action, Plaintiff will focus primarily on the period from 1/24/2006 through the Notice of Appeal 2/10/2009. The Plaintiff took over the prosecution as an Inventor, Pro Se in early 2006. Although the Office denied his Pro Se status for nearly a year and a half, the Plaintiff represented himself in all matters before the PTO and BPAI until issuance of the '119 patent 6/28/2011. Some evidence will necessarily refer to earlier dates to demonstrate the continuity of specific problems and prejudices expressed by the Examiner while the Plaintiff was represented by admitted patent attorneys in the first 3 years of the prosecution and then self-represented beginning in 2006. Other evidence will lack continuity due to file deletion.

13. The evidence will show a pattern in the prosecution of the '119 patent of multiple recurrent violations of the 35 U.S.C. laws and 37 C.F.R. rules with regard to Intellectual Property, as well as complete disregard for MPEP guidance and regulation based on 35 USC and 37 CFR. The evidence will show an entirely inconsistent application of those rules, laws, regulations and the uneven application of the patent process which discriminated against the Plaintiff's right to a monopoly on his intellectual property and specifically favored others referred to as "known commodities to the Office" by the Examiner in an Interview in December 200. The crass violation of accepted business practices, PTO best practices, and common courtesy are revealed throughout this case

along with a disturbing level of moral turpitude by the Examiner and her superiors. Plaintiff will illustrate multiple violations of 37 CFR 1.133 all the way to the Director of Patent's Office in an attempt to utilize 37 CFR 1.2 as an excuse for the Office's bad acts while the failure to treat the '678 application under the pro se rules or to follow the MPEP rules specifically regarding pro se applicants after 4/24/2006 is evident in every Office Action and communication. The denial of the Plaintiff's right to fair and equitable consideration and due process will be established while the lost, missing, forged and incomplete records from the '678 Image File Wrapper reported 5/2007 to the Plaintiff by SPE#2 as deliberate tampering to cause abandonment of the Plaintiff's application will be shown. A complete breakdown of supervisory audit and managerial oversight in the chain of command; and failure to act in good faith and within the spirit of the law from the Examiner and Supervisory Patent Examiners ("SPE") all the way up to the executive level of the PTO runs throughout the history of this case. The lengths to which the PTO and its agents were willing to go to disrupt the prosecution of the '678 application and/or force its abandonment are remarkable and flagrantly evident in the records as will be demonstrated. Because 35 U.S.C. 154 and all other statutes specifically governing patent terms do not address such situations with regard to Patent Term Adjustment, the applicant is seeking redress and an appropriate Patent Term Adjustment of at least 17-years from Date of Issue in the Federal District Court.

14. Exhibits B ("IFW""PAIR") and C ("Transaction History" "PALM") will be useful when reviewing this complaint to guide the chronology of events; however, some documents are missing from the record and/or have been substituted or merely lost and

will be produced from the Plaintiff's personal files if available. Evidentiary documents from one cellular telephone and one residential long distance telephone companies are being requisitioned with expected arrival in early to mid-2012 to demonstrate the phone numbers, dates, length of calls, and dates of incoming and outgoing calls and faxes between the Plaintiff and the Examiner, SPEs, and higher level management which will support the written documentation concerning telephonic negotiations and agreements found within the Plaintiff's fax cover pages, letters, amendments, remarks, comments and replies to Office Actions. Unless otherwise noted, dates referred to in this complaint will be the dates currently assigned to documents on the USPTO IFW, PAIR System for the '678 application as it appears today. Except for documents missing, deleted or never added to the '678 application file, documents referred to and provided as Exhibits are printed directly from the current online IFW for the '678 application. Many Exhibits are grouped by sequential date as they appear in the '678 IFW and in the order they download from the IFW for the '678 application – due to tampering in the Plaintiff's '678 PAIR file, some of the Exhibits are titled differently than what they actually contain. If the evidence does not require the entire document, page numbers will be referenced on the Exhibit cover page in those cases. Additional documents from another application IFW will be presented to show the inconsistency of prosecution of similar applications under the same SPE.

EXHIBIT KK – SPE#1 was focused on this application to the extreme detriment to the '678 application which had priority date.

15. It is expressly not the purpose of this action to assign culpability to any single agent under the direction of Commissioner of Patents nor is it the purpose of this action

to question or challenge the validity of any patent mentioned here or in the prosecution of the '119 patent. However, it is the Plaintiff's contention that a conflict of interest was established from the beginning due to SPE#1 concurrently supervising 2 Primary Examiners, one of whom was examining the Plaintiff's '678 application claiming a priority date of 6/26/2001 while a 2nd, more experienced Primary Examiner concurrently examined a similar application claiming a priority date from a PPA filed 8/6/2001 where said PPA was directly inspired by the Plaintiff's 6/26/2001 Intellectual Property after the applicant was given a complete copy of the Plaintiff's 6/26/2001 Provisional Patent Application on 7/10/2001. Although the Examiners and SPEs may have been unaware that Plaintiff had priority filing date and that his PPA was shared with the other applicant in an effort to create a business relationship, preferential treatment ensued to the benefit the other applicant and extreme detriment of the Plaintiff, due to familiarity in the Office with other applicant which created a conflict of interest for the SPE#1. The result of this conflict directly affected the Examination of the Plaintiff's '678 application bogging it down in rejections for many years. Numerous letters and emails were exchanged between the Plaintiff's attorney John Murnane of Baker Botts and Stuart Baker & Mark Waddell of Chadbourne & Parke, Attorneys for Purdue Pharma/Frederick and Mortimer Sackler regarding the Plaintiff's "Tamper Proof Delivery System" Provisional Patent Application filed 6/26/2001 describing a 3-component formula for moderate to severe pain involving a 1. agonist, 2. antagonist, and 3. an antagonist removal component of either botanical or pharmaceutical nature. While John Murnane expected to do business with Purdue Pharma or Purdue Frederick regarding the Plaintiff's Intellectual Property and awaited a meeting date, associates of Purdue Pharma/Frederick were, on August 6, 2001 filing three of their

own three component systems inspired by and similar to the Plaintiff's. Although John Murnane demanded the provisional patent be returned when it became obvious Purdue would not be doing business with the Plaintiff, the PPA was never returned nor guaranteed to be destroyed due to "proprietary data notes written on the Plaintiff's PPA." While the applications which were filed on 8/6/2002 were examined and granted allowance within a few years, the Plaintiff was refused even the barest of consideration. The other applicant was a "known commodity" of the Office and the Plaintiff was a complete unknown. While the Plaintiff's application was rejected as obvious again and again by his Examiner, the other three applications were issued patents within a few short years under the same Supervising Patent Examiner as the one who supervised the Plaintiff's examiner. While the Plaintiff struggled to protect that which he conceived and shared in a good faith effort to solve a long sought need and create a mutually beneficial business relationship, his use of botanical cathartics and methylnaltrexone as the 3rd component was rejected immediately without consideration as obvious, while the other 3 applications using botanical or chemical bittering agents, botanical or chemical irritants, and botanical or chemical gelling agents were not considered obvious and were granted patents and generated income while the Plaintiff's one patent was suppressed costing him a decade of lost business opportunity and hardship. The evidence presents a case of prima facie case obviousness of conflict of interest on the part of the SPE and the deliberate denial and destruction of an individual citizen's intellectual property in favor of a group of inventors who ultimately assign their patents to the same deep pocketed corporate entities who pay large fees to the office. While this would be considered contrary to community standards of honesty and good moral practice, the Commissioner of Patents

was unimpressed with and unmoved by the Plaintiff's plea for assistance taking an additional 2 years of the Plaintiff's time and opportunities and causing great discord in the Plaintiff's business and personal life.

- EXHIBIT HH – Interview Summary leading to allowance of similar patent
- EXHIBIT II – Letters/emails dtd 7/10/2001, 10/1/2001, 7/9/2002, 7/18/2002 discussing the release of Dr. John Farrell's 6/26/2001 PPA regarding a Tamper Proof Delivery System to Purdue for their consideration.
- EXHIBIT JJ – Transaction History/PALM, printed 5/22/2007 showing major differences with EXHIBIT C due to file tampering. An IFW printed from 5/22/2007 does not exist to the best of the Plaintiff's knowledge.

16. As evidenced by the Board of Patent Appeals and Interference 11/10/2010, a total of 2 Primary Examiners and 3 SPEs completely failed over 8 years from 2002 to 2010 to recognize and acknowledge the “patentable subject matter” in the specifications and claims of the ‘119 patent. Not only did they fail to fairly apply 37 CFR 1.75(d) (1); [R-5] – 2111 “Claim Interpretation: Claims must be given their broadest reasonable interpretation” but also the Examiners and SPEs completely failed to consider or apply MPEP 707.07(j) II “State when claims are allowable”/“Allowable except as to form [R-5]”. The fact that over 6 years from the first Office Action in 2004 to the 2010 Appeal, neither the Examiners and SPEs, nor the Art Unit Director, nor the Commissioner's Office staff member, who claimed to have thoroughly examined the ‘678 file never once suggested to the Plaintiff that 2 dependent claims could be added onto 2 independent claims resulting in an allowable patent is simply unacceptable since a review of numerous other pharmaceutical patents reveal that the Primary Examiner schedules and

conducts Telephone Interviews with the attorneys/inventors/employees for pharmaceutical companies and tells them which claims to cancel, which ones to amend or to incorporate into other claims. An example of this is an Examiner-Initiated Interview Summary in which the Examiner of an application inspired by the Plaintiff's provisional patent of 6/26/2001 was contacted by the Examiner on 7/17/2006. The Examiner's comments on the PTOL-413b say: "Continuation of Substance of Interview including a description of the general nature of what was discussed: to place the application in condition for allowance, it was suggested [by the Examiner] to: 1) incorporate claim 17 into claims 1, 23 and 25; 2) amend claim 25 to include an administering step; and 3) filing terminal disclaimers to co-pending applications. Applicant authorized the Examiner's Amendment, but suggested to cancel claim 25." A box is checked at the bottom that states: "It is not necessary for applicant to provide a separate record of the substance of the interview, since the interview directly resulted in the allowance of the application. The examiner will provide a written summary of the substance of the interview in the Notice of Appeal." The Plaintiff in this case repeatedly asked his Examiner to give him this same consideration, guidance, and assistance but she flatly refused saying it was forbidden by law. This 7/17/2006 interview summary put the application 10/213/921 filed 8/6/2002 in condition for allowance as US Patent 7,144,587 "Pharmaceutical Formulation Containing Opioid Agonist, Opioid Antagonist, and Irritant Agent". Two days later, 7/19/2006, the pro se applicant of the '678 application was cancelling every single one of his original claims which had a priority date of 6/26/2001 and replacing them with new claims on the direct and express advice and guidance of his Examiner. In the next Office Action dated 10/4/2006, the Examiner used the publication

number 2003/0124185 only as a 103 Obvious rejection of the Plaintiff's '678 application. The level of depravity required for a Federal Agency of the United States to treat an individual citizen inventor in such a way while hand-holding a corporate entity through an allowance is beyond comprehension.

- EXHIBIT GG - 6/2/04 - Examiner's Index of Claims – 1-27 rejected; 1/17/2006 Examiner's Index of Claims – 1-28 cancelled, 29-53 new claims rejected.

17. It is also notable that the first 4 years of prosecution through mid-2006, the '678 application was handled by Examiners and an SPE#1 (as a Primary Examiner) have allowed patents for the entity in paragraph above by the scores. There is a long history of collaboration between the Primary Examiner on '678 and SPE#1 for patents within the same technical center and class as the Plaintiff's, leading to an expectation of the '678 application being examined by those with at least ordinary skill in the art of narcotic pharmaceutical patent examination resulting in a recognition of the new formula claimed by Plaintiff Farrell. Instead, this familiarity was used against the Plaintiff and the application '678. A Boolean Search of Patents demonstrates the Primary Examiner on the '678 application had been an Assistant Examiner to the SPE#1 on the '678 application while he was a Primary Examiner on over 240 issued patents.

18. In March 2006, when the Plaintiff first became Pro Se, he left a series of voice mails to SPE#1, on the direct telephone line indicated on the last page of Office Actions, that he, the inventor of a "Tamper Proof Narcotic Delivery System" was now prosecuting the patent application Pro Se and by virtue of being dyslexic and exclusively an English speaker, he was having great difficulty discerning words and understanding the

Examiner's heavily accented spoken English during telephone interviews. The Plaintiff requested to be informed of the method by which he could be assigned a new Examiner or translator to make communication clearer. SPE#1 made no attempt at any time to return the Plaintiff's calls. Not one return call, ever. Additionally, SPE#1 did not review the case to determine if the Examiner was completing PTOL-413 or responding to Plaintiff's comments regarding telephone calls in which he was given instructions of substance. Further, SPE#1 did nothing to correct the Examiner when she completely denied the applicant the benefits of MPEP §707.07(j) by categorically stating that the Examiner was "barred by law from drafting or assisting in claim language". The Examiner never indicated in writing which claims would be allowed if submitted in an allowable way. She never offered constructive actions but only stark rejection of claims. She never offered definite suggestions for correction that she did not later renege on and reject. She never indicated the desirability of an interview nor recorded the extensive and substantive interviews that occurred over the more than 5 years the Plaintiff acted on his own behalf. Moreover, the Examiner never identified or stated dependent or cancelled claims which would be allowed if written as independent claims, a situation which, in fact, led to the application being allowed by the BPAI decision. The Examiner repeatedly made contradictory statements in interviews and in Office Actions which served to confuse the Plaintiff including advising and urging the Plaintiff to pursue RCEs and cancel all claims when it was absolutely contradictory to the Plaintiff's interests. Despite having notified the Office of his Pro Se status more than 5 times in 2006, the Examiner continued to refuse to treat the Plaintiff as Pro se at any time. The Examiner offered no assistance at all except to state in telephone calls after listening to the Plaintiff slowly and

carefully explain the science of Tamper Proof Narcotic Delivery System that she did in fact understand the '119 patent and found it deserving of her forthcoming allowance only to suffer complete and total memory loss of the interview when she issued Office Actions 3 months later prompting the Plaintiff to again call her to find out where she had gone wrong and explain the invention to the Examiner again. This cycle continued until the Plaintiff pursued relief from the Board of Patent Appeal and Interference that vindicated the Plaintiff's conclusion that the IP was indeed a patentable invention.

- EXHIBIT E – 1/24/2006 - Final Rejection – p.7 - SPE#1 – Tel: 571.272.0602
- (EXHIBIT - to be furnished by telephone company long distance charges and cell phone call details to demonstrate direct calls and direct faxes to and from the Office call center and the private direct voice and fax numbers to the Examiner and SPE#2 which did not route through the Art Center 1600 telecom system or fax machine)
- EXHIBIT F - 4/24/2006 - response to Final Office Action of 1/24/2006-indicates conversations with Examiner, includes letter revoking attorney's POA
- EXHIBIT G – 5/15/2006 – Rejection of 4/24/2006 Amendments, mailed to Baker Botts

19. Another of the series of violations which become evident when reviewing the Image File Wrapper is the total of four (4) PTOL-413s filed by the Examiner or SPEs despite frequent interviews of substance over a period of 4 years, between the Plaintiff, Examiner, and SPE#2. Although the Plaintiff ultimately turned to the Art Unit Director and then the Commissioner for Patents for assistance, the one call he received from each office was not recorded in the record either. In the early telephone calls with the

Examiner, when the Plaintiff was moving toward a Pro Se status, the Examiner informed the Plaintiff that the attorney representing the Plaintiff was, in her opinion, “obstructing progress and allowance” and “difficult to work with”. The Examiner ultimately admitted to numerous interviews in an endnote in the Examiner’s 10/9/2009, Reply to Appeal Brief, but Examiner attempted to characterize the calls as being “unscheduled” when in fact the Plaintiff frequently scheduled calls to review the amendments wherein the Examiner called the Plaintiff at a scheduled time. These calls took some time and often had to be broken up into sections due to the time-consuming and laborious language barrier which required the Plaintiff to repeat back to the Examiner what he thought she said and in which he had to have the Examiner spell words she was saying which were not understandable to a native English speaker. The Plaintiff acknowledged the general contents of each interview he had with the Examiner and SPE#2 in the cover pages, Amendments and Remarks sections of each reply he submitted with the amendments as they were suggested to him by the Examiner. However, the Office seems to have missed these remarks and never disputed them. According to the rules, Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete or accurate, the examiner may give the applicant a 1-month time period to complete the reply under 37 CFR 1.135(c) where the record of the substance of the interview is in a reply to a Non-Final Office action. There is even wording suggested ¶ 7.84: “Amendment Is Non-Responsive to Interview. The reply filed on [1] is not fully responsive to the prior Office action because it fails to include a complete or accurate record of the substance of the [2] interview. [3] Since the above-mentioned reply appears to be bona fide, applicant is given a time period of one (1) month or thirty (30) days from

the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment.” Extensions of this time period may be granted under 37 CFR 1.136(a). What is especially interesting about the Examiner’s note at the end of the “Reply to Appeal Brief” is that the Plaintiff made a point in his Appeal Brief that the SPEs failed to call him, in particular SPE#1 who ignored no less than 7 messages. The Examiner misinterpreted the statement like so many of the other misunderstood statements and facts in the Plaintiff’s Specification and Claims over 9 years were misunderstood.

- EXHIBIT B– Image File Wrapper/PTOL413s - 7/23/2007, 2/23/2011, 3/7/2011, 4/7/2011

20. Disconcerted that the SPE whose name and number the Plaintiff was instructed to call with questions failed to pick up the telephone and call him back, the Plaintiff on 4/24/2006 first faxed and then USPS Express Mailed, entirely on his own letterhead, his response to the 1/24/2006 Office Action which contained a plain language explanation of how his patent worked and the role of methylnaltrexone in it with a drawing of the oral dosage and a copy of a letter sent to Baker Botts dated 3/28/2006 to informing them he was revoking their representation of him with regard to the ‘678 application. The cover letter to the Examiner informed the Examiner the Plaintiff was representing himself as of 4/24/2006 and that he had no experience with the law or patents. This correspondence of 4/24/2006 contained only the Plaintiff’s letterhead, only his signature, his telephone number and his email address and an invitation to call him with any questions and a promise to follow up with her “next week”, indicating they had spoken previously. Although this correspondence and all correspondence following met the basic

requirements of 37 CFR 1.36, 1.32(a)(4), and 1.41 regarding the revocation of a Power of Attorney, the Plaintiff was not acknowledged as the Pro Se applicant at any time throughout the entire prosecution. Proper mailing address was not used until 7/2007, over 14 months since the Plaintiff first informed the Office in writing he was Pro Se. 35 USC § 26 indicates that despite not using the “official” Power of Attorney form, the POA was in fact in effect as of 4/24/2006. Again, in opposition to the 35 USC, 37 CFR and MPEP rules and guidance, the Examiner and SPE#1 flagrantly continued to withhold information from the Plaintiff by directing all Office Actions and Advisory Actions to the former attorney without copying Dr. Farrell. The delay in receiving the notifications presented an additional hindrance to the Plaintiff’s exercise of his rights because of his learning disabilities.

- EXHIBIT F - 4/24/2006 – Plaintiff’s first response to Office Action from 1/24/2006

21. In response to the Plaintiff’s 4/24/2006 reply to the 1/24/2006 Office Action – Final Rejection, the Examiner did not update the contact information or place a call to the Plaintiff to suggest to him he “may” use form PTO/SB/82 under 37 CFR 1.36. Nor did she tell him the ‘678 application was eligible to file a Notice of Appeal at that point. Nor did she tell him there was an Inventor’s Assistance Center (“IAC”) to assist pro se inventors like himself. Nor did she tell him he could see his own prosecution file on the Public PAIR system (in fact she told the Plaintiff later in the prosecution when he specifically asked about the “computer records” that only attorneys and PTO employees could have access and that he could not have access unless he hired a new attorney. Nor did she inform the Plaintiff he could access to the MPEP, 35 USC, and 37 CFR on the PTO website and should become familiar with the rules and statutes regarding his rights

and responsibilities as an American inventor, pro se. Nor did she disclose to Plaintiff the opportunity at his disposal to enshrine in the file his detailed recollection of phone interviews during which the Examiner made promises never kept or that he should be entering written submissions of the substantive telephone interviews which occurred between them since September 2005 to allowance either in a PTOL-413(a) submission or answering by letter. Neither did the Examiner submit the substantive contents of interviews (PTOL-413) as the Examiner was supposed to be filing (but did not) about their phone interviews. This Primary Examiner, under the supervision of SPE#1 and the Art Unit Director did none of these things. A statement from Plaintiff Farrell in the first paragraph of 4/24/2006 letter to the Examiner states: "I am sure that working together we can rectify the deficiencies," lending credibility to the Plaintiff's statement that he was receiving regular substantive advice by telephone from the Examiner. The Examiner was advising him on amendments to claim language but never once agreed to write a claim that would actually bring allowance. The Examiner gave hints and suggestions on the telephone on changes but refused to dictate claim language, much less write allowable claim language herself. The examiner completely failed to give good faith advice regarding rules of the Power of Attorney, the MPEP, the Independent Inventor's Hotline, the Plaintiff's status as a pro se, and the PTOL-413(a). The Examiner was fully aware that the Plaintiff knew nothing of the IAC Hotline and that she had become the sole source of information to the Plaintiff during the time she was supervised by SPE#1 which served to isolate the Plaintiff further. The Examiner and her SPEs, in short, took advantage of that position of sole source of information and the Plaintiff's position of isolation to deliberately delay the '678 application for another 4 years.

- EXHIBIT F - 4/24/2006 – Plaintiff's first response to Office Action from 1/24/2006

22. Following the 4/24/2006 reply from the Plaintiff, the only action by the Examiner was to send an Advisory Action (PTOL-303) on 5/15/2006 addressed to Baker Botts calling the Plaintiff's 4/24/2006 submission a "non-compliant amendment" along with a long note on it proclaiming: "the invention as a whole is prima facie obvious over the combined teachings of US '384 and Yuan" but the Examiner failed to send a copy to the applicant nor make the proper notation on the original or copies. In this case, the first of many, the Examiner violated 37 CFR 1.33 (c), MPEP 714.01(d) "Amendment signed by Applicant but not by Attorney" which requires: "Two copies of the action should be prepared, one being sent to the attorney and the other directly to the applicant. The notation" "Copy to Applicant" should appear on the original and on both copies." In this same 5/15/2006 Advisory Action (PTOL-303) the Examiner failed to follow the rule of law regarding Dual Correspondence because the following paragraph was not included in the notes as directed in MPEP 403 ¶4.01 Dual Correspondence" "Applicant has appointed an attorney or agent to conduct all business before the patent and Trademark Office. Double correspondence with an applicant and applicant's attorney will not be undertaken. Accordingly, applicant is required to conduct all future correspondence with this Office through the attorney of record." Not sending this correspondence to the applicant nearly lead to the abandonment of his intellectual property. It is suggested that the Examiner chose to rest on 37 CFR 1.2 as her protection from having to fulfill obligations under 35 USC §§131, 132. However, as stated above, the Plaintiff had in fact revoked the POA and should have been receiving all the benefits of prompt replies instead of being delayed by the Examiner's refusal to enter the change of address.

- EXHIBIT G - 5/15/2006 - Advisory Action to Baker Botts, not mailed to Plaintiff,

23. Following the 5/15/2006 Advisory Action mailed to Baker Botts address with no copy to the Plaintiff, the Examiner continued to speak with the Plaintiff when he called and to return his calls ultimately convincing him that in order to put his patent in a condition for allowance, he needed to "CANCEL ALL THE ORIGINAL CLAIMS and SUBMIT NEW ONES". She also advised him to send an RCE and Extension of Time and the required fees. The Image File Wrapper record for 7/19/2006 contains the record of this interesting entry where the Plaintiff sent by USPS Express Mail and via fax an amendment canceling all original claims and amending his statement as directed by the Examiner by telephone. Note the bottom of the fax cover page states: "Thank you for all your help and guidance. Please contact me directly on any issues or questions. And the page entitled "REMARKS" following the new claims states: "The applicant appreciates the Examiner's steadfast diligence and guidance in order to refine wording of the claims to ensure clarity." The Plaintiff also mentions again that he is not represented by counsel and has no legal knowledge. Due to the instruction and guidance of the Examiner, coupled with promises of allowance, the "Index of Claims" for '119 patent demonstrate that between 1/17/2006 and 9/27/2006, the original 28 claims disappeared completely and were replaced by a new set of newly rejected claims. Four years into prosecution, all the claims are thrown out on the advice of the examiner and rewritten. It can only be anticipated that the purpose of instructing the Plaintiff to cancel the original claims and submit new ones was an attempt on the part of the Examiner with the support of her SPE#1 to render the application permanently patentable due to "112 New matter" rejections. The Examiner failed to recognize the extreme diligence practiced by the

Plaintiff when writing the new claims as he spent hours and hours reviewing the provisional patents and specifications to ensure nothing new was introduced. This did not stop the Examiner from stating that New Matter had been introduced on 7/17/2006 when the new claims were submitted and citing 112 New Matter rejections in each subsequent Office Action until finally, without explanation, withdrawing two of the 112 rejections in the Examiner's Answer to the Appeal Brief. Despite 4 years of 112 New Matter rejections, the BPAI overturned all the 112 rejections as they reviewed the PPAs and agreed that in fact the Plaintiff had not added new matter.

- Exhibit H – 7/19/2006 – USPS Express Mail Package to PTO & P. 1 Fax Cover Inventory
- Exhibit GG – 6/2/2004 – 3/21/2008 Examiner Index of Claims Index (1/17/2006 & 9/27/2006)

24. In July 2006, just prior to submitting the cancellation of original claims and newly written claims, the Plaintiff called the PTO Legal Department because he still had not heard back from SPE#1, TP regarding the advisability of such substantial changes as he was advised to make by the Examiner by telephone. During conversation with the Legal Department, an attorney at the PTO informed him of the Inventor's Assistance Center to assist inventors – this was the first the Plaintiff had been told of such a resource despite numerous calls with the Examiner and voice mail questions posed to the SPE#1. The Plaintiff also learned for the first time from the Legal Office the terms “reconstruction by hindsight” and “pro se”. The Plaintiff was facing a deadline despite having filed an RCE and Extension of Time and so was not able to avail himself of the advice from the retired SPEs at the IAC until after he submitted his 7/19/2006 response. The Plaintiff began

using Hindsight reconstruction in his replies to Office Actions after this and availed himself to the Inventor's Assistance Center Call Center ("Hotline") staffed by retired Senior SPEs from many Art Units.

25. The Plaintiff's reward for following the Examiner's guidance and canceling all the original claims was the 10/4/2006 Office Action addressed again just to the former attorneys who received it 10/10/2006 and eventually forwarded it to the Plaintiff dramatically shortening Plaintiff's time to respond in violation of 37 CFR 1.33(a).

- EXHIBIT I – 10/04/2006 PTO Office Action

26. This Office Action dropped the reference to patent '384 Kaiko for the 103(obvious) rejection and brought up a new citation for grounds of a 103 rejection. The removal of the '384 rejection was not explained in the Office Action, it was simply gone. The new citation upon which the Examiner built a house of hindsight 103 obviousness was referenced in the Office Action as simply: "2003/0124185", to once again reject the claims in the '119 patent as obvious in light of '185 and an article. With no other information other than the number 2003/0124185 to go on, the Plaintiff assumed it referred to a foreign patent and called the Hotline for help. The Hotline was able to identify the number as the Publication number for a Provisional Patent Application filed 8/6/2001 and point out the Plaintiff's application had priority as a defense. The Plaintiff simply and politely pointed out in his 12/30/2006 Response to the 10/4/2006 Office Action his priority date and said nothing else about the attempt to mislead and confuse him. Plaintiff believes if he had taken the bait and argued against the citation, he would have ended up losing his intellectual property permanently in a 102 due to the fact that

the cited reference received a Notice of Allowance the next day and the newly patented material would then forever have precedence over his despite the origins of the idea and his priority on filing.

- EXHIBIT J – References Cited by Examiner – not part of Office Action

27. Also advice obtained from the Hotline instructed the Plaintiff in steps to change the address and Power of Attorney in a more formal manner. Later that month on 10/17/2006, Baker Botts petitioned to be removed as counsel. The Petition was never granted by the Office of the Director.

- Exhibit I - 10/04/2006 PTO Office Action
- Exhibit K - 10/17/2006 PETITION TO WITHDRAW submitted by Baker Botts
- EXHIBIT L - 11/06/2006 Plaintiff; Summary of Telephone Interview not recorded by Examiner while Examiner was still treating Plaintiff as if he was represented by Baker Botts and directing all mail to Baker Botts.

28. The Plaintiff's 12/30/2006 response to the 10/04/2006 Office Action included the official form accepted, but not required by the PTO, to change in the Power of Attorney and mailing address and was USPS Express Mailed exactly like the 4/24/2006 and 7/19/2006 responses to Office Actions before. However, instead of entering the Power of Attorney and the change of address, the Plaintiff's 12/30/2006 response apparently disappeared. The Image File Wrapper for 1/1/2007 through 6/7/2007 shows no activity at all although the 12/30/2006 response was in the possession of the PTO in its entirety. The Plaintiff received no response to his 12/30/2006 reply despite speaking with the Examiner

and leaving her messages on several occasions. The Notice of Non-Compliance regarding the 12/30/2006 response was mailed on 6/8/2007 according to the record and the cover page with the Plaintiff's mailing address. But in a 6/07/2007 fax the Plaintiff makes reference to a 5/29/2007 response to a Non-Compliance letter from the PTO. On page 3 again reference is made to the 5/29/2007 (Remsen/Room TC 1600) letter and points out the execution of the change in the Power of Attorney from the 12/30/2006 submission is appreciated and requests claims and remarks from that submission be entered into the file history. The Plaintiff called the Examiner had assured Plaintiff her answer was forthcoming. It was only later discovered by the Plaintiff while preparing his Appeal Brief in early 2009 that inexplicably the records for 6/07/2007 had been copied over from a 3700 Technical Center file with the highlighted notation in gray "Copied from 11183678 on 5/20/2008". The "lost" copies show the entire original response as clear as the day it was mailed to the PTO on 12/30/2006. Now, CFR 1.251 – Unlocatable file and CFR 1.59 – Expungement of Info or copy of papers comes into play because the Plaintiff was expressly informed by SPE#2 that the 12/20/2006 Claims and Amendments were lost.

29. When the Plaintiff called the Inventor Hotline to confirm he had not missed an March or April Office Action and for the real story surrounding all the confusion with the '678 application the Plaintiff was told the records for the '678 application had disappeared and the plaintiff immediately began making calls to SPE#2 Michael Woodward begging for help in May 2007. The SPE#2's first message left on voice mail was to inquire as to why he was being bothered about an application marked "abandoned

property.” The Plaintiff called SPE#2 back immediately and forcefully impressed upon him that he was quite incorrect in his assessment that the ‘119 patent was abandoned because continuous negotiations were ongoing between the Plaintiff and the Examiner during the first six months of 2007. The Examiner had in no way indicated she did not have the 12/30/2006 documents or that the file was designated ‘abandoned’. In the first call between SPE#2 and the Plaintiff, the SPE was convinced at the sincerity of the Plaintiff and became concerned about the obvious discrepancy between the computer records he was seeing at the PTO and the information shared by the Plaintiff about the ‘678 application. The SPE informed the Plaintiff that he needed to investigate the details of what had transpired and promised to advise the Plaintiff with the results. At the conclusion of the phone call the SPE wanted to know why the Plaintiff had not been following his own record on the PAIR system all along. The Plaintiff explained that although he had previously asked the Examiner about how the Hotline advisers were referring to the records when he called for assistance from the Inventor Hotline, told him only attorneys and PTO employees could have access and he’d have to hire a new attorney to gain access. This was just one of many misleading statements and prevarications made by the Examiner during the prosecution of the ‘119 patent. SPE Woodward then explained to the Plaintiff how to access and view the Public PAIR system for the first time in over 18 months of the Plaintiff prosecuting the ‘678 application as a Pro Se. Until then, June 2007, the Plaintiff had never seen the PAIR system or his record on it. The subsequent investigation did confirm that in fact the record had been created to indicate that the intellectual property of the ‘119 patent had been aged to make it appear abandoned. The SPE did not assign blame or responsibility

but had become convinced by the results that the '678 application file had to be repaired which he attended to immediately and personally. Were it not for a period of time in May that even the Independent Inventors Hotline specialists could not locate the electronic record for the '119 patent this patent would have been lost forever. The SPE#2's last communication with the Plaintiff was a voice mail message stating, "I don't know why this application has been handled so badly; but it was." There was no mention of appealing the Examiner's rejections to the BPAI or any other constructive language outside of "repairing" the '678 file records and bringing the application out of abandonment. The several conversations that occurred between SPE#2 and the Plaintiff on the results of the investigation and the repair of the file history were not summarized or recorded in the Image File Wrapper.

- EXHIBIT M – 12/30/2006 USPS Express Mail to Art Unit 1600
- EXHIBIT JJ has addressed the inconsistencies in the IFW for '678 in 2007.

30. On 6/7/2007, according to the "altered" TFW, the Plaintiff submitted a response to the Notice of Non-compliance dated 6/8/2007 regarding his 12/30/2006 response. The Plaintiff then had to resubmit the amendments on 8/8/2007. In addition to the loss of time during 2006, the '678 application now had endured another 8 month Office delay. And, now, the 5th year came and went on 6/26/2007 without any attempt what-so-ever from the SPEs to contact the now pro se applicant regarding a petition to make the application "Special", contrary to MPEP 707.02 "Applications up for 3rd action & 5-year applications – designate special".

- EXHIBIT N - 6/07/2007 Plaintiff Response to a 5/29/2007/6/8/2007 Non-Compliance Letter

- EXHIBIT O - 6/07/2007 Mailed copy of Response to Non-Compliance Letter
- EXHIBIT P– 6/08/2007 Notice of Non-Compliance for 12/30/2006 Amended Claims
- EXHIBIT R– 7/18/2007 Faxed claims to SPE M Woodward
- EXHIBIT Q – 6/11/2007 – Messed up file copied over from 11/183678 on 5/20/2008 a few weeks after Plaintiff writes blistering letter to Art Unit Director on 4/4/2008

31. The 9/25/2007 Office Action dropped the 103 rejections completely with no explanation, leaving only 112 (New Matter and Written Description) rejections. The New Matter rejections were actually created by the Examiner when she convinced the Plaintiff to file an RCE and Time Extension and cancel and rewrite all the claims in the 7/19/2006 response. Upon receipt of the 9/25/2007 Final Office Action, the Plaintiff was so enthused that he had at long last traversed the 103 Obvious rejection that he immediately called the Examiner to discuss how to traverse the 112s. The retired SPEs at the Independent Inventors Hotline told him 112s were last-ditch efforts to end a patent prosecution. The Plaintiff wanted to ensure he responded correctly to this Final Office Action. When his calls and messages to the Examiner were ignored in late September and early October of 2007, the Plaintiff worked diligently to write a response traversing the 112s by reviewing the PPAs and '678 application Specifications to prove he had not added New Material nor did any Written Description issues remain that could not be remedied.

- EXHIBIT T – 9/25/2007 Office Action – only 112 left to traverse

32. On 10/15/2007, prior to responding to the 112 rejections from the 9/27/2007 Office Action, the Plaintiff wrote a fax cover and a two page letter to SPE#2 Michael Woodward and added the 9 pages of his proposed response and faxed it to Mr. Woodward's office fax with a request that it be reviewed and passed on to the Examiner and added to the official file system. He also wanted the SPE to advise on the best strategy to gain allowance and address the myriad of promises of allowance made by the Examiner to the Plaintiff only to have her turn around three-months later with a new Office Action and a new set of rejections as if the phone calls never occurred. The Plaintiff wondered how the Examiner could suffer such complete memory loss in such a short time.

- EXHIBIT U - 10/15/2007 Faxed strategy questions to SPE#2

33. SPE#2 did not contact the Plaintiff as requested nor did he place the fax in the record. As a result of being brought to the attention of the SPE, the Examiner did return the Plaintiff's calls and arranged to speak with the Plaintiff regarding his proposed response to the 9/25/2007 Office Action which he expected to lead to allowance. During several phone calls the Examiner and Plaintiff went through the 112 rejections carefully. The Examiner claimed during these interviews that she was looking at the Specifications from both of the original PPAs and '678 application and agreed page by page, line by line that there was no material introduced after all and that the 112 Written Description rejections were also going to be withdrawn. On a few minor items where the Plaintiff tried to make things clearer for the Examiner (who had great difficulty with the

pronunciation of the English language and a limited scientific vocabulary) two point were conceded by the Plaintiff and removed from the '678 application.

34. With the Examiner's language problems and the Plaintiff's dyslexia, telephone interviews were laborious with much repetition. When available, the Plaintiff's wife, a former remedial English teacher, listened on a speaker telephone to help translate what was being said often asking the Examiner to repeat or even slowly spell out what she had said or asking her to speak slowly one word at a time so the Plaintiff and his wife could fully understand what she was saying. On the last phone call regarding the response to the 9/25/2007 Office Action, the Examiner, after again assuring the Plaintiff he'd satisfied her concerns regarding 112 New Matter thereby putting the application in condition of allowance followed her assurance with a new requirement for allowance in the form of a Quality Assurance Committee specifically for narcotic formula applications to which she and her SPE would have to present the final amendments to the '678 application before getting approval to allow it. The Examiner presented it as consisting of a number of individuals. Although suspicious at this new obstacle to be traversed at this late stage in the prosecution, the Plaintiff eagerly offered to travel to the Office to defend his IP before this new committee but was told he would not be needed. When the Examiner left for vacation, she promised the Plaintiff allowance on the condition an RCE was submitted along with the amendments they had discussed and agreed upon directly to the Examiner as well as the promise to stand up and defend his IP to this committee. Plaintiff spoke with the Independent Inventors Hotline who told him that an appeal would take a couple of years but if the Examiner had in fact promised allowance after having been taken

through the PPAs and application and agreeing that what she thought was new matter was in fact already part of the record to then go ahead with the RCE. The Hotline however, had no knowledge of a Quality Assurance Committee for narcotic pain medications only. To have finally overcome the 103 obvious rejections and be reduced to 112(a) was a major accomplishment after 8 years. To now have a guarantee from the Examiner of allowance was the final step. Throughout the October-November and early December 2007 the Plaintiff and Examiner finally formalized each agreed citation in the Office Action into a formal written response that had already gained the Examiner's final approval in telephone interviews.

35. The response to all of the remaining 112 items were identified and systematically addressed in interviews with the Examiner and prepared for the Plaintiff's December 21, 2007 response. In light of past promises and guarantees of allowance from the Examiner on previous occasions the Plaintiff phoned one last time to confirm the response was ready for submission. The topic of the comparable cost of the RCE verses Appeal Board options came up in the conversation and the Examiner became insulted and indignant at the suggestion of any alternative to her prescribed and agreed to terms for allowance. It was mutually agreed that the Plaintiff would immediately submit the written response with an RCE to the Examiner on December 12, 2007.

- EXHIBIT V - 12/12/2007 Transmittal Form to PTO Formal response to Sept. Office Action

36. The Notice of 12/21/2007 for Non-Compliance of claims submission is yet another glaring example of how reliant the Plaintiff was upon the Examiner for guidance

at this late stage of the prosecution. Another Transmittal form was sent 12/27/2007 to correct the problems.

- EXHIBIT W - 12/21/2007 Non-Compliant Claims
- EXHIBIT X – 12/27/2007 Transmittal Form with Claim Modifiers submitted

37. The allowance promised during negotiations throughout the autumn of 2007 never arrived. Instead on 3/28/2008 a new Office Action arrived with the same 112 rejections from previous actions only now with a new round of 102 & 103 rejections. A cursory comparison between the Plaintiff's responses of the 12/27/2007 Office Action response and the Appeal Brief filed almost two and a half years later are almost exact mirror images. The BPAI decision overturned the Examiner on every 112 rejection cited.

38. The 3/27/2008 Office Action with new 102, 103 and the same 112s, cited yet another new reference and article written in German over which the '678 application was now held to be obvious. The Plaintiff concluded he had been deliberately deceived into filing the RCE on the insistence of the Examiner. In December 2007 the Examiner was aware of the 10/15/2007 fax to M Woodward with options that offered the alternatives of taking the case to the Appeal Board or RCE with the promise of allowance. Sadly if the Plaintiff had rejected the Examiner's false promise that she would grant the allowance following his 12/27/2007 amendments and response, Plaintiff would have gone before the BPAI in 9/2007 with only 112 rejections to overcome. A cursory comparison between the Plaintiff's responses of the 12 / 2007 Office Action response and the Appeal Brief filed almost two and a half years later are almost exact mirror images. The BPAI decision overturned the Examiner on every 112 rejection cited.

- Exhibit Y - 3/27/2008 PTO Office Action
- Exhibit F - Appeal Brief to the Board of Patent Appeals and Interference)

39. After consulting with the retired SPE members of the Inventor Assistance Center the Plaintiff was advised to directly contact the Art Unit Director for the 1600 Technical Center. The Inventor Assistance Center informed the Plaintiff that the Art Unit Director had the authority to independently review and allow any application in the art unit. A review of this letter will give a brief overview of the multiple violations committed by the PTO to delay the Plaintiff's application from becoming an issued patent for years.

40. The now flagrant prevarications made by the Examiner regarding allowance to the Plaintiff during the October-November-December 2007 negotiations regarding the 9/25/2007 Office Action response, were just more broken promises revealed by the arrival of the 3/27/2008 Office Action which had the usual 112 rejections, and brought back 102s and 103s with new citations based on Oshlack '088. These same rejections were repeated in the 9/12/2008 Office Action Made Final. The outrage of the Examiner's audacity of first reducing objections to 112s in the 9/25/2007 Office Action, then negotiating allowance for the 12/27/2007 Plaintiff's Response, and then bringing up all new citations for 102 and 103 rejections on 3/27/2008 prompted the Plaintiff to submit a 4/4/2008 letter to the 1600 Art Unit Director seeking review, intersession, allowance, and a new Examiner.. The Art Unit Director telephoned the Plaintiff one time to report he was assigning senior staff to fully investigate the matter and make recommendations to him for appropriate action. The Director was never heard from again, nor did he issue a PTOL-413 recording the substance of the call. However, it is remarkable that just a few

weeks later, on 5/20/2008, documents from the Plaintiff's Image File Wrapper and documents from another inventor's Image File Wrapper (11/183,678-abandoned) in the 3700 Mechanical Engineering Art Unit were copied over into the Plaintiff's Image File Wrapper going back to 6/7/2007. The Plaintiff questions the accuracy of the IFW because the Gray Line across the bottom of the 6/7/2007 Plaintiff's reply could have been applied at any time and the SPE#2's statement that the 12/30/2006 Reply to an Office Action which included the Power of Attorney form was missing at some point which was why the Notice of Non-compliance was delayed by 5 months is difficult to believe given the time stamped and clean copy of the 12/30/2006 is in the IWF and the Plaintiff was speaking with the Examiner during the first half of 2007.

- EXHIBIT Z - 4/04/2008 - Letter to 1600 Art Unit Director

41. The letter to Mr. Kisliuk was prompted by the events of the proceeding years as a pro se and was directed more specifically to the events following the Final rejection of 9/25/2007 which had, without any explanation at all [in violation of MPEP 707.07(f) ¶ 7.38.01 and 37 C.F.R. 1.104] dropped the all 103 Obvious rejections the Examiner had claimed, from the inception of the application but dropped and then brought back in various incarnations since the initial Non-final Office Action dated 6/4/2004 on the '678 application. The 9/25/2007 Office Action contained only 112 New Matter and Written Description rejections easily traversed by evidence contained within both the PPAs and claims and specifications of the '678 application. Ironically it required the BPAI to ultimately reverse every 112 rejection raised by the Examiner.

42. In the second paragraph of the 5/21/2008 response to the 3/27/2008 Office Action the Plaintiff specifically pointed out that the Examiner had on the December 2007 promise of allowance. The Plaintiff again discredited all the issues in the Office Action and did not amend any of the claims. He then awaited the promised action from the Art Unit Director that never came.

- Exhibit AA - 5/21/ 2008 Transmittal Form and Plaintiff Response to 3/27/2008 Office Action

43. Another Final Office Action dated 9/21/2008 arrived with the 112, a 102 & 103 rejections. Since no intervention had occurred by the 1600 Art Unit Director the Plaintiff took the additional step of directly contacting the Commissioner's Office for assistance. On September 12, 2008 a letter was submitted to Hon. John Doll then Commissioner for Patents. A staffer, John Barlow, called once in response to the letter to Mr. Doll.

- EXHIBIT BB - 9/21/2008 PTO Office Action)
- EXHIBIT CC - 9/12/2008 Faxed letter to Commissioner of Patents John Doll)

44. In 9/12/2008, a Final Office Action with the now familiar 112, 102 rejection & 103 rejections arrived. Since no intervention had occurred by the Art Unit Director as a result of the 4/4/2008 letter and phone call from the Art Unit Director promising follow-up, the Plaintiff took the additional step of directly contacting the Commissioner's Office for assistance making numerous phone calls on 9/12/2008 and in the days and weeks following. The Plaintiff also sent a letter to Commissioner John Doll. A staffer, John Barlow, called once in response to the letter to Mr. Doll. Another staffer, David Wiley sent a letter 10/27/2008 to the Plaintiff referring to the Plaintiff's letter of 9/12/2008 as

being dated 7/17/2008. amounted to no action to be taken by the Commissioner but did acknowledge the lack of action from the 1600Art Unit Director's Office. Mr. David Wiley from Mr. Doll's office responded with a perfunctory cover your ass (CYA) letter on 10/27/2008 stating what had ultimately become so obvious, that the BPAI was the only option left. Strangely, the letter refers to the Plaintiff having sent a letter to Mr. Doll on 7/27/2008 but it is obvious from the records, including a print out of Mr. Doll's contact information with numerous calls to the office noted on it from 9/12/2008 until 11/27/2008 that the letter was in fact prompted by the 9/12/2008 Final Rejection. The tone of the letter clearly indicated that assistance from the Commissioner would not be considered or forthcoming.

- EXHIBIT CC – 9/12/2008 – Letter to Commissioner Doll
- EXHIBIT DD - 9/12/2008 – Notes regarding numerous calls to the Commissioners office
- EXHIBIT EE - 10/27/2008 Wiley Response from Commissioner's Office

45. On 11/18/2008, perhaps as a result of the Plaintiffs letter and phone calls to the Commissioner's Office, a new Non Final Office Action arrived. Abruptly and without explanation, the Examiner rescinded the Final Office action with 112, 102 & 103 rejections and replaced it with a Non-Final Office Action with only 112 & 103 rejections. In this action the Examiner demonstrated a complete lack of comprehension of the intellectual property and even proposed that the invention was comparable, and therefore obvious, to a four-component formula of her own design. Since the reasoning had descended from the ridiculous to the sublime it became abundantly clear that the only recourse left to the Plaintiff was the BPAI.

- EXHIBIT DD - Sept. 2008 Contact Sheet Record of contact with the Commissioner's Office
- EXHIBIT FF - 11/18/2008 PTO Office Action

46. Although the MPEP - Appendix R § 10.23 Misconduct - thoroughly addresses the instances of misconduct which could be attributed to attorneys or agents, and even Pro Se inventors, no such MPEP applies to Examiners, SPEs and the management and executive staff of the PTO despite the multiple violations, mismanagement, failure to respond to requests for intervention and oversight and the complete breakdown of management responsibilities in this case. 37 CFR §10.111 directs patent practitioners to "avoid even the appearance of impropriety" however, this Plaintiff was treated with such disrespect and disregard for his basic rights that perhaps the Court should consider additional rulemaking for the USPTO employees and officers given the original intent of the patent law and the current atmosphere of complex and arbitrary application of rules and procedures which tend to benefit the deep pockets. MPEP 714.25 addresses Discourtesy on the part of Applicants and Attorneys. The methodology of conducting business with the PTO requires ritualistic formulaic written niceties to the examiner thanking them despite the fact they have offered little or no assistance at all or in cases the Examiner is deliberately delaying allowance, but no such rules apply to the PTO staff who offer nothing but discourteous service and refusal to answer questions honestly and completely or return phone calls to applicants has not been discovered in any catalog, rule, regulation, or code by this Plaintiff.

47. When the Plaintiff discussed his concern with losing his patent term due to the long pendency, the Examiner continually and repeatedly reassured him that the months and years would be returned at the end of the prosecution process. Examiner stated there is a procedure for such things and to “not worry” – obviously yet another gross misrepresentation.

48. The Examiner strenuously objected to the Plaintiff proposal of taking his case to the BPAI in December 2007. The Examiner expressed great offence and insult that the Plaintiff was even contemplating such a step. Having attempted to get intervention up to the highest level of the Office, the Plaintiff, again at the sole mercy of the Examiner, chose to attempt an appeal to the BPAI after having been warned on numerous occasions by the Inventor’s Assistance Hotline and the Examiner that the BPAI would hold him to the same level of practice as an admitted patent attorney, a particularly daunting proposition for one who has struggled through educational attainments and daily challenges of severe learning disabilities. After this point and in hindsight at several points earlier in the prosecution; however, the Plaintiff now recognized he had been deceived into filing Requests for Continued Examination (RCEs) instead of going to the BPAI on the verbal promise of allowance after protracted telephonic negotiations and agreements with the examiner regarding exact wording and forthcoming allowance. The examiner and SPE were well aware that the Plaintiff was entirely ignorant of the MPEP rules in general and the rules regarding telephonic interviews specifically.

49. Although the MPEP offers numerous suggested wording for paragraphs to be used within the scope of 37 CFR 1.75(d)(1); [R-5] – 2111 “Claim Interpretation” and 707.07(j) including ¶¶ 7.43, 7.43.01, 7.43.02, 7.43.04 “Suggestion of Allowable Drafted

Claims, Pro Se” or ¶ 7.97, the Examiner refused to acknowledge any patentable subject matter contained in the Plaintiff’s 3 component formula utilizing opioid agonists, antagonists and methylnaltrexone. This failure on the part of the agent, supervisors and managers of the agency to provide audit and oversight led to the Plaintiff being forced into numerous RCE actions while the Examiner was assuring the Plaintiff by telephone he would obtain allowance and “get his time back” after he met the specific conditions annunciated by the Examiner. The Plaintiff did not learn until after the ‘119 patent was allowed that the RCEs filed throughout the prosecution denied him from receiving a full patent term due to the stipulations in 35 UCS 154. It is notable that even in the Notice of Allowability dated 3/7/2011, page 6, the Primary Examiner states, to paraphrase: “I am issuing this because the BPAI is making me.” It is also notable that the very simple amendments required to make the ‘119 patent allowable, i.e., correcting status identifiers; canceling four claims and moving the dependent claims regarding methylnaltrexone into the independent claims 29 and 41, resulted in 19 claims being allowed after having been rejected for the better part of a decade. These amendments should have been offered to the Plaintiff as suggestions to obtain allowance long before the application was forced into its first RCE status.

50. The supervisors along with higher management, although previously made aware of issues with the ‘678 application, were completely useless and uninvolved when the Plaintiff received the 11/10/2010 BPAI Decision and subsequently called the 1600 Art Unit SPE Quality Assurance Specialist (QAS) and left a message asking guidance on what his next step in the process of allowance should include. The QAS, so certain that

he, the Examiner, and SPE#3 who had written and signed off on the 3/4/2009 Pre-Brief Appeal Decision affirming and upholding all cited rejections and sending the case to the Board of Appeals, called back and started the conversation by telling the Plaintiff how disappointed he was for the Plaintiff. The only remaining step involved appealing to the Federal Court if he wanted to keep fighting for his patent. The QAS commended the Plaintiff on all his "hard work" and was "just as disappointed" as the applicant. The Plaintiff was confounded by the QAS's comments. The applicant asked the QAS to get his copy and had him turn to pages 15-17 of the BPAI report and pointed out to him that, in fact, the Examiner had been overturned on all 112 citations and the vital 103 issues and that in fact it was up to the QAS to now guide the Plaintiff through the amendments necessary to conclude allowance. The QAS was left speechless but then was forced to admit the Plaintiff had won his case entirely on the merits of his IP and the 53-page Appeal Brief the Plaintiff carefully wrote and rewrote over a period of several months. The QAS finally became very friendly and helpful, the first time anyone other than the retired SPEs at the Independent Inventor's Hotline and staff in the Office of the Board of Patent Appeals had ever been helpful in any way.

51. The QAS tried to send the Plaintiff back to deal with the Examiner who had for so many years lied to him in phone calls knowing there would be no accountability since the Plaintiff had been kept ignorant of the rules regarding interviews by the Examiner allowing her to make promise after promise but not keep any since they were "not on the official record" but the Plaintiff insisted and told the QAS he would only speak with the QAS or the SPE. The Plaintiff took the opportunity to explain at length to the QAS that

after so many years of her flouting the rules and taking advantage of his innocent naivety and lack of legal and patent procedure knowledge, he would not speak with the Examiner again because he did not trust her anymore to advise or conduct the final allowance properly and feared she would somehow cause the case to be reopened to prosecution. The Plaintiff explained to the SPE-QAS this position had previously been clearly communicated up the chain of command at the PTO all the way to the Commissioner's Office. This was now the seventh or eighth time the Plaintiff had explained these facts to an official of the PTO, the first being the unreturned calls to the assigned SPEs as well as the letters to Art Unit 1600 Director Kisliuk and the Commissioner.

52. Section 154(b)(4)(A) of Title 35 provides that "[a]n applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the Eastern District of Virginia within 180 days after the grant of the patent. Chapter 7 of Title 5 shall apply to such action." Section 702 of Title 5 further provides, in pertinent part, that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof." Having received a dissatisfactory patent term adjustment in light of the protracted prosecution and actions and inactions by the Examiner supported by the assigned SPEs to the higher management up to and including the Office of the Commissioner for Patents and the statutory prohibitions contained within 35 USC 154 to remedy the situation satisfactorily, Plaintiff Farrell hereby brings the present action for

judicial review of the PTO's behavior throughout the prosecution of the '678 application as well as the calculation of patent term adjustment for the '119 patent.

53. Under Section 154 of Title 35 of the United States Code, the Director of the PTO must grant a patent term adjustment in accordance with the provisions of section 154(b), which states, in pertinent part, that "[t]he Director shall proceed to grant the patent after completion of the Director's determination of a patent term adjustment under the procedures established under this subsection, notwithstanding any appeal taken by the applicant of such determination 35 U.S.C. § 154(b)(3)(D).

54. In order for an aggrieved party to obtain a full hearing and complete consideration of intellectual property denied allowance, the patent applicant, as explained to the Plaintiff by the Examiner on numerous occasions, must file a Request for Continued Examination ("RCE") to continue the prosecution of an application rejected for any reason when the rejection is made FINAL at the discretion of the Examiner. The wording in 35 U.S.C. 154 creates specific statutory exceptions against patent term adjustments for any aggrieved applicant that determines his intellectual property was delayed and denied due process and equal consideration due to the agents and officers of the PTO acting and/or failing to act in an official capacity within the rules and procedures of the PTO and seeks redress of issues that withheld allowance. Even when an applicant must ultimately resort to the appeal process, as the Plaintiff did over the strong objection and advice of the Examiner, to obtain a patent on valid intellectual property. The RCE mechanism and procedure is part of that process. 35 § U.S.C. 154 fails to account for extraordinary and

inappropriate delays attributable to the failure of the Examiner and SPEs to follow the most basic rules contained in the MPEP which forced the Plaintiff's counsel and the Plaintiff, pro se to submit RCEs. The result in this case is a near total loss of patent term adjustment.

55. In determining patent term adjustment under 35 § U.S.C. 154, the Director is required to extend the term of a patent for a period equal to the total number of days attributable to delay by the PTO. The Director determined that the '119 patent is entitled to 621 days of patent term adjustment and issued the '119 patent reflecting that determination. However, the laws governing patent term adjustment fail to account for or reflect the total number of days directly attributable to the failure of the PTO to apply the rules of examination evenly, account for mistakes by the Office resulting in delay, the repetitive flouting of MPEP rules by agents and officials of the PTO, misinformation given to applicants by PTO agents and the failure to supervise or act accordingly by the PTO and its agents which forced the Plaintiff to file Requests for Continued Examination. The number and nature of the delays and RCEs attributable directly to the PTO, its agents and its officers along with the circumstances described herein which resulted in the decade-long pendency of the '119 patent are overwhelming and directly responsible for the shortened term this patent ultimately received and must presently endure.

56. The Plaintiff has not entered a request for correction of the Director's determination in accordance with 37 C.F.R. 1.705(d) from the PTO because it was determined by officials in the Patent Term Adjustment Office that due to the "statutory

restrictions and prohibition” contained within 35 USC 154 regarding RCEs, the perfunctory step involved in 37 C.F.R. 1.705(d) is unnecessary, unproductive, and no more than a distraction from the ultimate goal of a substantial patent term adjustment for the patent ‘119 to give it the full patent term it deserves. Although officials within the Patent Term Adjustment Office appeared sympathetic to the Plaintiff’s plight, the fact remains that the Plaintiff was denied the right to receive equitable treatment, examination, and consideration by the Patents division of the USPTO due to his status as an independent inventor unaffiliated with any “known commodity.” The USPTO failed at every level to practice common courtesy or humane consideration in this case they demand of practitioners often causing the plaintiff great distress and humiliation as a result of the prejudicial, malicious and deliberately misleading treatment he received despite his requests for the involvement and oversight of the supervisory staff and management. The Plaintiff is forced to file today, Pro Se, to demonstrate with the evidence within the record of the delay attributable to the PTO not covered in 35 USC 154 or any other statute regarding patent term adjustments.

57. The Plaintiff in this complaint is aggrieved at the numerous instances of disregard and violation by the PTO, its agents and officials of the clear laws, rules, and guidance of MPEP, Chapter 37 C.F.R., and Title 35 U.S.C. Plaintiff asserts that by one or another means improper training and oversight, gross negligence and conflict of interest, the PTO subverted a multitude of laws, regulations, and procedures related to the patent process during the examination and prosecution of the ‘119 patent. The Plaintiff prevailed in the face obstinate and intractable action and inaction by the PTO, enduring an extensive 9

years and 2 days of examination and received an inadequate patent term adjustment as a direct result of delay attributable to the USPTO. The shortened term will deny the Plaintiff the ability to fully exercise his monopoly and has, over the years and currently continues, to cost license and assignment opportunities the '119 patent and its owner had every right to expect.

CLAIM FOR RELIEF

58. The allegations of the paragraphs 1-57 are incorporated into this claim for relief as if fully set forth herein.

59. The patent term adjustment for the '119 patent, as determined by the Director under 35 U.S.C. § 154(b), and as set forth on the face of the patent is 621 days. The determination of this 621day patent term adjustment is in error because the PTO, and the Director acting in his official capacity, improperly calculated the length of the delay period attributable to the PTO. The BPAI determined the Examiner failed to sufficiently identify patentable subject matter in the claims in the '678 application. This failure by the Examiner and resulting absence of a *prima facie* case for rejection from the inception of the '678 application means that the Plaintiff Farrell is an aggrieved party and has been unjustly deprived of the benefit of a patent by the agent and the agency charged with the responsibility of regulating and administering intellectual property in the United States.

60. Statute 35 U.S.C. 154 denies the '119 patent a term adjustment to make this patent "whole" because of statutory requirements imposed on PTO in rules and procedures. This Statute does not consider or encompass cases and eventualities where supervised or unsupervised Examiner error, undetected and uncorrected by management personal after years abetted the deliberate delay and obvious obstruction, is reversed on the review and written decision by the Board of Patent Appeals and Interference, wherein, the Examiner is ultimately forced desist and allow the issue of the patent.

61. Within the rules and procedures of the PTO, in order to overcome the hurdle of a rejection made Final, an applicant must submit an RCE to keep the case alive, unwittingly depriving the applicant of term adjustment even when the BPAI finds the examiner is in error, ultimately favoring the appellant and allowing the patent. While this Statute might have made sense when the patent term law was changed from 17 years from issuance to 20 years from first filing minus the average time of 35 months to issuance plus a patent term adjustment, there is no consideration in this statute for situations such as presented in this action where the Examiner error obstructed and blocked allowance until forced to issue allowance by impartial higher authority at the BPAI. Plaintiff cannot imagine anyone drafting this legislation ever conceived of the potential for such delays and obstructionist tactics as those employed by this Examiner unrelentingly against the specific intellectual property embodied within the '119 patent, which has such important application within a highly specialized industry. Indeed since the conversion to conform to treaty obligations the PTO has worked to maintain the timeframe of approximately 17 years for US Patents.

62. The '119 patent is not subject to a disclaimer of term. Thus the period of patent term adjustment is not limited under 35 U.S.C 154(b)(2)(B).

63. The correct patent term adjustment needs to reflect the facts of this case and acknowledge that profound issues related to the mishandling and cascade of individual and organizational failures and errors on the part of the PTO in this prosecution of the '119 patent exist and have resulted in injury to the aggrieved Plaintiff Farrell.

64. Accordingly, the Director's determination that '119 patent is entitled to only 621 days of patent term adjustment, as evidenced in the PTO Decision, is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance or spirit of the law and in excess of statutory jurisdiction, authority, or limitation. At this juncture only the Federal Court can make this Plaintiff and the intellectual property whole.

PRAYER FOR RELIEF

Wherefore, Plaintiff demands judgment against Defendant and respectfully requests that this Court enter Orders:

A. Changing the period of patent term adjustment for the '119 patent from 621 days to 17 years from the Date of Issuance and requiring the Director to extend the term of the '119 patent to reflect a decision by this Court in this instance that the only

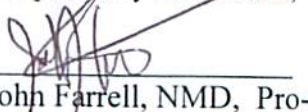
equitable solution is to draw from the historical precedent and grant the Plaintiff Farrell a full seventeen year patent term.

B. Should this Court see fit to demonstrate and reinforce the egregious nature of the mismanagement by the PTO and its agents and injury caused by the PTO upon the Plaintiff to the Director and the PTO as a whole that this behavior in the present and future applications will not be ignored, rewarded, or tolerated, the Plaintiff Farrell is willing to accept an addition of 3 years to the term of the '119 patent beyond the 17 years from the Date of Issuance requested in (A.) above bringing the term of the '119 patent to a full 20 years. It is hoped that a demonstration by this Court decision to the PTO that such activities as were committed against the aggrieved party and the '119 patent will motivate the PTO to institute policy changes in examiner and supervising examiner training and audit procedures that will guarantee that grievances such as the ones raised here will not be repeated against another patent applicant or application.

C. Granting such other and future relief as the nature of the case may admit or require and as may be just and equitable.

Dated: December 23, 2011

Respectfully Submitted,


John Farrell, NMD, Pro-se

jjf40@columbia.edu
P.O. Box 19803
Asheville, NC 28815
Telephone 828-707-3504